

REMARKS

The present response is to the Office Action mailed December 9, 2008, and no amendments to the claims have been made.

Applicants note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicants request that the Examiner carefully review any references discussed below to ensure that Applicants' understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

Applicants also note that the remarks presented herein have been made merely to clarify the claimed embodiments from elements purported by the Examiner to be taught by the cited reference. Such remarks, or a lack of remarks, are not intended to constitute, and should not be construed as, an acquiescence, on the part of the Applicants: as to the purported teachings or prior art status of the cited references; as to the characterization of the cited references advanced by the Examiner; or as to any other assertions, allegations or characterizations made by the Examiner at any time in this case. Applicants reserve the right to challenge the purported teaching and prior art status of the cited references at any appropriate time.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

PRIOR ART REJECTIONS

Rejection Under 35 U.S.C. §102

The Office Action rejected claims 1-21 and 24-30 under 35 U.S.C. § 102(e)¹ as being anticipated by U.S. Patent No. 7,334,379 (*Siegel*). Applicant respectfully traverses because a *prima facie* case of anticipation has not been established.

With regard to claim 1 and the corresponding dependent claims, Applicant respectfully asserts that no anticipatory rejection under § 102(e) as been made to the method claims. The Examiner has not established where Siegel teaches any method, but has only recited the components of a system of Siegel. Claims 1-10 and 24-27 are directed to methods for automatically filling tablets into tablet containers comprising at least one tablet compartment for receiving tablets. However, the rejection only discusses a system and the acts of claims 1-10 and 24-27 are not specifically addressed. Thus, with regards to claims 1-10 and 24-27, the Office Action fails to present a proper *prima facie* case of anticipation including a full and reasoned explanation as to all of the claimed elements. *See In re Lee*, 61 USPQ2d 1430, 1432-33 (Fed. Cir. 2002) that requires such full and reasoned explanations as follows:

... the agency tribunal must present a full and reasoned explanation of its decision. The agency tribunal must set forth its findings and the grounds thereof, as supported by the agency record, and explain its application of the law to the found facts. The Court has often explained:

The Administrative Procedure Act, which governs the proceedings of administrative agencies and related judicial review, establishes a scheme of "reasoned decision making." Not only must an agency's decreed result be within the scope of its lawful authority, but the process by which it reaches that result must be logical and rational.

Allentown Mack Sales and Service, Inc. v National Labor Relations Bd., 522 U.S. 359, 374 (1998) (citation omitted). This standard requires that the agency not only have reached a sound decision, but have articulated the reasons for that decision. The reviewing court is thus enabled to perform meaningful review within the strictures of the APA, for the court will have a basis on which to determine "whether the decision was based on the

¹ Because *Siegel* is only citable under 35 U.S.C. § 102(e) Applicants do not admit that *Siegel* is in fact prior art to the claimed invention but reserve the right to swear behind *Siegel* if necessary to remove it as a reference.

relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971). Judicial review of a Board decision denying an application for patent is thus founded on the obligation of the agency to make the necessary findings and to provide an administrative record showing the evidence on which the findings are based, accompanied by the agency's reasoning in reaching its conclusions. See *In re Zurko*, 258 F.3d 1379, 1386, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001) (review is on the administrative record); *In re Gartside*, 203 F.3d 1305, 1314, 53 USPQ2d 1769, 1774 (Fed. Cir. 2000) (Board decision "must be justified within the four corners of the record"). [Emphasis added.]

Accordingly, the rejection applied to claims 1-10 and 24-27 also fails to meet the minimum requirement of providing an administrative record showing that the evidence on which the Office Action's conclusion that those claim are anticipated.

Applicant respectfully asserts that there is a fundamental difference between the disclosure of Siegel and what is claimed in independent Claims 1 and 11. In accordance with Applicant's understanding, Siegel discloses a pharmaceutical product packaging machine/system that comprises a computer to control the devices of the machine (col.4/line 26-30). However, Siegl is silent on when, how, and which relevant data is received and/or processed with the machine/system. As such, Siegel does not teach or suggest that the machine/system is configured for or includes: "receiving a patient order containing a patient identification and at least one prescription comprising prescription data regarding the types of tablets to be taken by the patient and instructions for taking said tablets," as recited in claim 1; or "reception means for receiving a patient order containing a patient identification and at least one prescription comprising prescription data regarding the types of tablets to be taken by the patient and instructions for taking said tablets," as recited in claim 11. Since Siegel does not teach or suggest such a receiving act or reception means, claim 1 and 11 cannot be anticipated.

Additionally, Siegel discloses (col. 3, line 64 through col. 4/line 3; col. 6/line 20-27) that a bar code reader may be employed to read a code from the product package card immediately after the card has been filled with the medication so that the card may be specially associated with the particular patient dose. Thereafter a label specific to that card may be printed. As such, Siegel teaches that the patient data is not

associated with the card until after the card has been filled. The teaching of Siegel implies the fact that the computer receives what tablets to fill into which product package card for which patient, and the computer controls the devices to fill the card. Thus, the card is only associated with this relevant patient/tablet information after being filled with tablets. Thus,

Contrary to the teachings of Siegel, the presently claimed method in claim 1 receives the relevant patient/tablet information and instructions for taking the tablets before "allocating the prescription data and patient identification to respective tablet containers," as recited in claim 1. As such, the presently claimed method requires receiving certain data and then allocating the data to respective tablet containers. Nothing in Siegel teaches such method steps performed in the claimed series. In fact, Siegel only associates the filled card with patient/tablet information. Also, the system of claim 11 has "allocation means for allocating the prescription data and patient identification to respective tablet containers," which is not taught or suggested by Siegel.

Contrary to the teachings of Siegel, the present invention allocates the relevant patient/tablet information and instructions for taking the tablets as early as possible in the stage of the filling process. This allows the method to provide the tablet containers with increased security to indeed provide the right tablets to the right patient. In Siegel, a software or hardware error could link the bar code information read by the bar code reader from the product package card after the card has been filled with the tablets to the wrong relevant patient/tablet information stored in the computer. As such, the label printed on the card would comprise wrong data what could lead to a dramatic outcome for the patients. Accordingly, the early as possible coupling of relevant patient/tablet information and instructions for taking the tablets with the tablet container can provide a surprisingly strong improvement with regard to the reliability that the right number and type of tablets are packaged in the tablet container that is marked for the determined time for the patient to take the tablets.

In any event, Siegel clearly does not disclose a method or system configured to receive and process "instructions for taking said tablets" before the tablet compartments

are filled. Thus, each and every element of the presently pending claims are not taught or suggested by Siegel.

In view of the foregoing, the Office Action has not established a *prima facie* case of anticipation with regard to the presently pending claims. Thus, Applicants respectfully request that the rejection under 35 U.S.C. § 102(e) be withdrawn.

Rejection Under 35 U.S.C. § 103

The Office Action rejected claims 22 and 23 under 35 U.S.C. § 103(a) as being unpatentable over Siegel in view of U.S. Patent No. 6,449,921 (Kim). Applicant respectfully traverses because a *prima facie* case of obviousness has not been established.

This § 103(a) rejection relies on the teachings of Siegel anticipating claims 1 and 11 under § 102(e). However, Siegel does not teach or suggest each and every element of claims 1 and 11 as explained above. As such, the remarks regarding Siegel recited above are relevant to the rejection under § 103(a), and such remarks are incorporated herein by specific reference. Additionally, Kim does not teach or suggest the same elements recited above that Siegel do not teach or suggest, and thereby, Kim does not correct the deficiencies of Siegel. Accordingly, the combination of Siegel and Kim do not teach or suggest each and every element of claims 1 and 11.

In view of the foregoing, the Office Action has not established a *prima facie* case of obviousness with regard to the presently pending claims 22 and 23. Thus, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe the claims as amended are in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, or which may be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 9th day of June, 2009.

Respectfully submitted,

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